feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice."

[65 FR 76929, Dec. 8, 2000]

§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention. etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofuran, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofuran drugs by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofuran, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV–100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofuran, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements of this section: *Provided,* That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Pitman-Moore, Inc.	Bacitracin zinc	Chickens, turkeys, swine, pheasants, quail, and cattle.	Sec 558.78	Sec. 558.78.
A. L. Laboratories, Inc	...do	Chickens, turkeys, pheasants, and quail.	...do	Do.
A L Laboratories, Inc., Fermenta Animal Health Co..	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558 76	Sec. 558 76.
Elanco Products Co	Hygromycin B	Chickens and swine.	Sec. 558.274	Sec 558.274.
Do	Tylosin	Chickens, swine, and beef cattle.	Sec. 558.625	Sec 558 625.
Sanofi Animal Health, Inc.	Erythromycin	Chickens, turkeys, and swine.	Sec. 558.248	Sec. 558 248.
The Upjohn Co	Lincomycin	Chickens	Sec. 558.325	Sec. 558.325.
Pfizer, Inc	Oleandomycin	Chickens, turkeys, and swine	Sec. 558.435	Sec 558 435.
Hoechst-Roussel Agri-Vet, Inc	Bambermycins	Chickens	Sec. 558 95	Sec 558.95.
Elanco Products Co	Tylosin and sulfamethazine	Swine	Sec. 558.630	Sec 558.630
American Cyanamid Co., Fermenta Animal Health Co., Feed Specialties Co., Inc., Pfizer, Inc., PennField Oil Co., and VPO, Inc..	Chlortetracycline	Chickens, turkeys, swine, and cattle	Sec. 558.128	Sec 558 128
Merck Sharp & Dohme Research Labs., and Solvay Veterinary, Inc.	Procaine Penicillin	Chickens, turkeys, swine, pheasants, and quail.	Sec. 558.460	Sec. 558 460
Pfizer, Inc., PennField Oil Co.	Oxytetracycline	Sec. 558 450	Sec. 558 450	Sec 558 450
American Cyanamid Co	Chlortetracycline and sulfamethazine.	Cattle	Sec 558.128	Sec. 558 128.
Sanofi Animal Health, Inc.	Erythromycin	Cattle	37 mg per head per day.	Sec. 558.248
Hoffman-La Roche, Inc	Sulfadimethoxine and ormetoprim	Chickens and turkeys..	Sec. 558 575	Sec. 558.575
Pfizer, Inc.	Oxytetracycline and neomycin.	Chickens, turkeys, swine, and calves.	As provided in paragraph (g)(2) of this section	As provided in paragraph (g)(2) of this section
American Cyanamid Co and Pfizer, Inc.	Chlortetracycline, sulfamethazine, and penicillin.	Swine	do	Do.

Drug sponsor	Type A article	Species	Use levels	Indications for use
Boehringer Ingelheim Vetmedica, Inc..	Chlortetracycline, sulfathiazole, and penicillin.	....do	.... do	Do.

(2) The following is a list of drug combinations permitted when prepared from antibacterial Type A articles listed in paragraph (g)(1) of this section. Drug combinations listed in subpart B of this part name their sponsors and are incorporated herein by reference since they are safe and effective by contemporary standards, or such sponsors have been notified of any additional safety or efficacy data required on an individual basis:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Boehringer Ingelheim Vetmedica, Inc.	Chlortetracycline and arsanilic acid.	Swine	10 to 50 g/ton and 0.005 to 0.01 percent	Enhancement of growth and feed efficiency.
American Cyanamid Co	Chlortetracycline and sulfamethazine	Cattle	Sec. 558.128	Sec. 558.128.
Pfizer, Inc , PennField Oil Co., and VPO, Inc.	Oxytetracycline and neomycin base	Chickens	50 g/ton and 35 to 140 g/ton.	Prevention of diseases from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis)
Do	..... do	Chickens (first 2 weeks).	50 to 100 g/ton and 35 to 140 g/ton	Prevention of early chick mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	.. .. do	Chickens	.. ...do	To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at time of stress As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of bluecomb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of nermycon-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis)

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do	do	do	100 to 200 g/ton and 35 to 140 g/ton	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	do	Turkeys	50 g/ton and 35 to 140 g/ton.	As an aid in the prevention of disease from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	do	do	50 to 100 g/ton and 35 to 140 g/ton.	To extend periord of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality prevention of hexamitiasis As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	do	Turkeys (first 4 weeks).	do	As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	do	do	100 to 150 g/ton and 35 to 105 g/ton	As an aid in reducing mortality in birds which have suffered an attack of air-sacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).
Do	do	Turkeys	do	As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis)

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do	do	do	100 to 200 g/ton and 35 to 140 g/ton.	Control of bluecomb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	do	do	200 g/ton and 70 to 140 g/ton.	Control of infectious synovitis. For the treatment of bacterial enteritis and bluecomb (mud fever or nonspecific enteritis).
Do	do	Swine	50 g/ton and 35 to 140 g/ton	As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).
Do	do	do	50 to 150 g/ton and 70 to 140 g/ton.	As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.
Do	do	Calves	50 g/ton and 35 to 140 g/ton.	As an aid in the prevention of bacterial enteritis (scours).
Do	do	do	100 g/ton and 70 to 140 g/ton	As an aid in the treatment of bacterial enteritis (scours).
Do	do	do	8 to 100 mg/gal and 100 to 200 mg/gal reconstituted milk replacer.	As an aid in the prevention of bacterial diarrhea (scours)
Do	do	do	40 to 200 mg/gal and 200 to 400 mg/gal reconstituted milk replacer.	As an aid in the treatment of bacterial diarrhea (scours).
The Upjohn Co	Lincomycin, amprolium, and ethopabate.	Chickens	Secs. 558.58 and 558.325.	Secs. 558 58 and 558 325
Do	Lincomycin and zoalene.	do	Secs. 558.325 and 558.680.	Secs 558 325 and 558.680.
Do	Lincomycin, amprolium, ethopabate, and roxarsone	do	Secs. 558.58, 558.325, and 558.530.	Secs. 558.58, 558.325, and 558.530.
Do	Lincomycin, monensin, and roxarsone.	do	Secs. 558 325, 558.355, and 558.530	Secs 558.325, 558.355, and 558 530.
Do	Nicarbazin and procaine penicillin.	Chickens	0 01 to 0.02 percent and 2 4 to 50 g/ton.	Do.
Do	Nicarbazin and bacitracin methylene disalicylate.	do	0.01 to 0.02 percent and 4 to 50 g/ton	Do.
Do	Nicarbazin, bacitracin methylene disalicylate, and roxarsone	do	0.01 to 0 02 percent, 4 to 50 g/ton, and 0 0025 to 0 005 percent.	Do.
Do	Nicarbazin, procaine penicillin, and roxarsone.	do	0 01 to 0.02 percent, 2.4 to 50 g/ton, and 0.0025 to 0.025 percent.	Do.

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do	Amprolium and bacitracin methylene disalicylate.	Chickens and turkeys.	0.0125 to 0 025 percent and 4 to 50 g/ton	Secs 558.55 and 558.76.
Do	Amprolium, ethopabate, and bacitracin methylene disalicylate.	Chickens	0.0125 to 0.025 percent, 0 0004 percent, and 4 to 50 g/ton.	Secs. 558 58 and 558 76.
Do	Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone	do	0.0125 to 0.025 percent, 0.0004 percent, 4 to 50 g/ton, and 0.0025 to 0 005 percent.	Secs. 558.58, 558.76, and 558.530.
Do	Amprolium and procaine penicillin	Chickens and turkeys.	0.004 to 0.025 percent and 2 4 to 50 g/ton	Secs. 558.55 and 558 460.
Do	Amprolium, procaine penicillin, and roxarsone.	Chickens	0.004 to 0 025 percent, 2 4 to 50 g/ton, and 0.0025 to 0 005 percent	Secs. 558.55, 558.460, and 558.530.
Do	Amprolium, ethopabate, procaine penicillin, and erythromycin	do	0 0125 to 0.025 percent, 0.0004 percent, 2.4 to 50 g/ton, and 4.6 to 18.5 g/ton.	Secs. 558 58 and 558.460.
Do	Amprolium and erythromycin.	do	0.0125 to 0.025 percent and 4 6 to 18 5 g/ton	Sec 558.55.
Do	Amprolium and ethopabate.	do	0 0125 to 0 025 percent and 0.0004 percent	Sec. 558 58
Do	Amprolium, arsanilic acid, and erythromycin.	do	0 0125 to 0.025 percent, 0.01 percent, and 4 6 to 18 5 g/ton	Sec 558 55
Do	Amprolium, arsanilic acid, and ethopabate.	do	0.0125 to 0.025 percent, 0.01 percent, and 0.0004 percent	Sec 558.58.
Do	Amprolium, ethopabate, and bacitracin methylene disalicylate	do	0 0125 percent, 0 004 percent, and 4 to 50 g/ton.	Do.
Do	Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone	do	0 0125 percent, 0 004 percent, 5 to 35 g/ton, and 0.00375 percent.	Do
Pitman-Moore, Inc.	Bacitracin zinc, amprolium, and ethopabate.	do	4 to 50 g/ton, 0 0125 to 0.025 percent, and 0 0004 percent.	Prevention of coccidiosis Growth promotion and feed efficiency Sec.558.78
Do	Bacitracin zinc, amprolium, ethopabate, and roxarsone	do	4 to 50 g/ton, 0.0125 to 0.025 percent, 0 0004 percent, and 0.0025 to 0.005 percent.	Prevention of coccidiosis. Growth promotion and feed efficiency Improving pigmentation. Sec. 558.78.
Do	Bacitracin zinc and arsanilic acid.	Swine	10 to 50 g/ton and 0.005 to 0 01 percent.	Increased rate of weight gain and improved feed efficiency
Merck Sharp & Dohme Research Labs.	Amprolium, ethopabate, procaine penicillin, and roxarsone.	Chickens	0.125 to 0 025 percent, 0.0004 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent	Secs. 558.58, 558 460 and 558.530

Drug sponsor	Type A article	Species	Use levels	Indications for use
A L. Laboratories, Inc	Zoalene and bacitracin methylene disalicylate.	Chickens	0.0125 percent and 4 to 50 g/ton.	Sec. 558.680.
Do	Zoalene, roxarsone, and bacitracin methylene disalicylate.	do	0.0125 percent, 0.005 percent, and 4 to 50 g/ton	Do.
Do	Zoalene and bacitracin zinc.	do	0 0125 percent and 4 to 50 g/ton.	Do.
Do	Zoalene, roxarsone, and bacitracin zinc.	do	0.0125 percent, 0.0025 to 0.005 percent, and 4 to 50 g/ton.	Do.
Do	Zoalene and penicillin	do	0 0125 percent and 2.4 to 50 g/ton.	Do.
Do	Zoalene, roxarsone, and penicillin.	do	0.0125 percent, 0.0025 to 0 005 percent, and 2.4 to 50 g/ton.	Do.
Do	Zoalene, arsanilic acid, and bacitracin methylene disalicylate or bacitracin zinc	do	0.0125 percent, 0.01 percent, and 4 to 50 g/ton.	Do.
Do	Zoalene, arsanilic acid, and penicillin.	do	0.0125 percent, 0.01 percent, and 2.4 to 50 g/ton.	Do
Do	Zoalene, and bacitracin methylene disalicylate.	do	0 004 to 0 0125 percent and 4 to 50 g/ton.	Do
Do	Zoalene, roxarsone, and bacitracin methylene disalicylate.	do	0.004 to 0.0125 percent, 0.0025 to 0.005 percent, and 4 to 50 g/ton.	Do.
Whitmoyer Labs, Inc	Carbarsone and bacitracin.	Turkeys	Sec. 558.120	Sec. 558.120
Elanco Products Co.	Hygromycin B and tylosin	Chickens	8 to 12 g/ton and 4 to 50 g/ton.	Sec. 558 274.
Do	do	Swine	12 g/ton and 10 to 100 g/ton.	Do.
A L. Laboratories, Inc.	Nitarsone and bacitracin zinc.	Turkeys	0.01875 percent, 4 to 50 g/ton.	As an aid in the prevention of blackhead. To increase rate of weight gain and improve feed efficiency.

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.35 Aklomide.

(a) *Approvals.* Type A medicated articles: to 053501 in § 510.600(c) of this chapter, as follows:

(1) 50 percent aklomide.

(2) 20 percent sulfanitran and 25 percent aklomide.

(3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.

(4) 50 percent aklomide and 10 percent roxarsone.

(b) *Related tolerances.* See § 556.30 of this chapter.

(c) *Conditions of use.* It is used in feed for chickens as follows:

(1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).